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BEFORE
THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROSLIN INSTITUTE (EDINBURGH)
Inventors: Keith Henry Stockman Campbell and Ian Wilmut

Appeal 2010-006828
Application 09/225,233
Technology Center 1600

Before FRED E. McKELVEY, SALLY G. LANE, and MARK NAGUMO, *Administrative Patent Judges*.

NAGUMO, *Administrative Patent Judge*.

DECISION ON APPEAL

A. Introduction[1, 2]

Keith Henry Stockman Campbell[3] and Ian Wilmut ("Roslin") timely appeal under 35 U.S.C. § 134(a) from the final rejection[4] of claims 155-159 and 164, which are all of the pending claims. We have jurisdiction. 35 U.S.C. § 6. We AFFIRM.

The subject matter on appeal is cloned cattle, sheep, pigs, and goats. This is the second time this application has come before us for decision on appeal. As explained *post*, many complications arising in the earlier appeals[5] are no longer present, due to abandonment of the companion 862 Application[6] and to the nature of the claims now presented.

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[1] Application 09/225,233, *Quiescent Cell Populations For Nuclear Transfer*, filed 4 January 1999, claiming benefit under 35 U.S.C. §§ 120 and 371 via intermediate applications to 30 August 1996, and the benefit under 35 U.S.C. § 119(a) back to 31 August 1995 ("233 Application"). The real parties in interest are listed as the Roslin Institute (Edinburg), and, by virtue of licensing agreements, Start Licensing, Inc., a wholly-owned subsidiary of ViaGen; Geron Corp., and Exeter Life Sciences, Inc. (Appeal Brief, filed 8 September 2009 ("Br."), 2.)

[2] Heard 1 November 2012, before a court reporter. The transcript is cited as "Tr."

[3] We note with regret the untimely passing of Dr. Campbell on 5 October 2012.

[4] Office action mailed 10 November 2008.

[5] Our previous decision in this case, *Ex parte Campbell*, 2007-1617 (BPAI 30 January 2008) ("*Campbell I*,"), was a combined decision with companion 09/658,862 application, ("862 Application"), because markedly distinct arguments were not raised to the rejections in the two applications, which were filed and prosecuted in parallel with one another.

[6] The 862 application was abandoned on 16 September 2008.

The appealed subject matter is covered by representative claims 155 and 164, which read:

> 155. A live-born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs, and goats.

(Claims App., Br. 38.)

> 164. The clone of any of claims 155-159, wherein the donor mammal is non-foetal.

(Claims App., Br. 38.)

The "donor mammal" donates the cell nucleus that directs development of the clone.

Claims 156-159 depend from claim 155 and further specify that the claimed clones are limited to clones of cattle, sheep, pigs, and goats, respectively.

We decide three ultimate questions in this appeal:

(1) Are the claimed clones patentable subject matter under 35 U.S.C. § 101?

Assuming arguendo that the claimed clones are patentable subject matter,

(2) Are the claimed clones anticipated, or would they have been obvious, in view of prior art clones created from embryonic donor mammals?

(3) Are the claimed clones anticipated, or would they have been obvious, in view of prior art mammals created by in vitro fertilization procedures?

Accepting that a clone is, in a sense that we shall explore in some detail *infra*, a "copy" of the donor mammals specified by the appealed claims, Question (1) may be restated as follows: "under what circumstances, if any, is a copy of a pre-existing thing, patentable subject matter within the meaning of the applied statute?" Put still another way, is a copy of a living mammal patentable subject matter, or is it a "product of nature," and thus subject to the exceptions to patentable subject matter recognized by the Supreme Court?

The rejections giving rise to Question (2) are "hybrid" rejections under §§ 102/103 that illuminate the scope of the claims by inquiring into the nature of the differences, including the origins of the differences, between the original and the copy. The rejections giving rise to Question (3) are also hybrid rejections, and they illuminate structural differences between similar originals and copies within the scope of the claims.

Previous Proceedings

In *Campbell I*, claim 163 of the then-copending 862 application[7] was similar in scope to currently appealed claim 155 (the donor must be non-

[7] Application 09/658,862 derived from a separate application filed in Great Britain on the same day as the ultimate priority application of the 233 Application, and was the national stage of an international application filed on the same day as the corresponding international application that led to the 233 Application.

embryonic), while claim 155 of the 233 Application was similar in scope to currently appealed claim 164 (donor required to be non-embryonic and non-foetal). We affirmed the rejection for lack of patentable subject matter, emphasizing the necessity of comparing the claimed clones to the nuclear donor, rather than to the set of all donors (*Campbell I*, para. bridging 14-15), and we designated the affirmance as a new ground of rejection.
We affirmed the rejections over prior art clones in which the donors were embryonic; we reversed the rejections over prior art mammals created by sexual reproduction; and we affirmed the enablement rejection of claims encompassing clones of mice, rabbits, horses, and rats.

Roslin reopened prosecution of the application before the Examiner, amending the claims by removing the species challenged for enablement. Roslin also removed the recitation of express process steps involved in the cloning of cells from a donor mammal. What remains are the appealed claims to live-born clones of previously existing cattle, sheep, pigs, and goats.[8]

An extended discussion of the technical background in cloning was presented in our first opinion, *Campbell I*. We repeat and expand portions of that background to provide a technological context for the discussion that follows. Although the details of the cloning procedure are not recited in the claims, they inform our understanding of the nature of the art and the

[8] Following oral argument, briefing was invited on the implications of the recent decision *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (cert. granted, 133 S. Ct. 694 (30 Nov. 2012)) ("*Myriad*"). Order issued 5 November 2012. Roslin filed a Supplemental Brief 26 November 2012 ("Supp. Br.").

claimed invention, although we do not find it necessary to repeat many of the findings and considerations related to the enablement of clones of those species that are no longer claimed.

When asked at oral argument, counsel for Roslin indicated that certain objections to the findings of fact in *Campbell I* would be addressed in the course of the arguments to the Board. (Tr. 3, ll. 10-14.) Review of the transcript and record, however, reveals that no findings of technological facts were identified as leading to errors in our conclusions. Thus, the disagreements center on our application of law to the facts of this case.

The Rejections

A number of double patenting rejections over previously issued patents have been obviated by the filing of terminal disclaimers on 9 May 2009, which have been accepted. (Ans. 2 § 6.)[9]

Examiner maintains the following grounds of rejection:[10]

A. Claims 155-159, and 164 stand rejected under 35 U.S.C. §101.

B1. Claims 155, 156, and 164, drawn to clones of cattle, stand rejected under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Sims.[11]

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[9] The filing of a terminal disclaimer, of course, is not a concession of obviousness. *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (2007) (citation omitted).

[10] Examiner's Answer mailed 4 January 2010 ("Ans.").

[11] Michelle Sims and N.L. First, *Production of Calves by Transfer of Nuclei from Cultured Inner Cell Mass Cells*, 91 Proc. Nat'l. Acad. Sci. USA 6143-6147 (1994).

C1. Claims 155, 157, and 164, drawn to clones of sheep, stand rejected under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of McLaughlin.[12]

D1. Claims 155, 158, and 164, drawn to clones of pigs, stand rejected under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Prather.[13]

E1. Claims 155, 159, and 164, drawn to clones of goats, stand rejected under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Yong.[14]

B2. Claims 155, 156, and 164, drawn to clones of cattle, stand rejected under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Zinn.[15]

C2. Claims 155, 157, and 164, drawn to clones of sheep, stand rejected under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Aldrich.[16]

D2. Claims 155, 158, and 164, drawn to clones of pigs, stand rejected under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Matte.[17]

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[12] K.J. McLaughlin et al., *In vitro Embryo Culture in the Production of Identical Merino Lambs by Nuclear Transplantation*, 2 Reprod. Fertil. Dev. 619-622 (1990).

[13] Randall S. Prather, Michelle Sims, and Neal L. First, *Nuclear Transplantation in Early Pig Embryos*, 41 Biol. Reprod. 414-418 (1989).

[14] Z. Yong *et al.*, *Nuclear Transplantation in Goats*, 35 Theriogenology 299 (1991).

[15] R.A. Zinn, *Influence of Processing on the Comparative Feeding Value of Barley for Feedlot Cattle*, 71 J. Anim. Sci. 3-10 (1993).

[16] G.C. Aldrich et al., *The Effects of Endophyte-Infected Tall Fescue Consumption and Use of a Dopamine Antagonist on Intake, Digestibility, Body Temperature, and Blood Constituents in Sheep*, 71 J. Anim. Sci. 158-63 (1993).

E2. Claims 155, 159, and 164, drawn to clones of goats, stand rejected under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Ortega-Reyes.[18]

Rejections B1, C1, D1, and E1 are based on prior art disclosures of clones from embryonic cattle, sheep, pigs, and goats, respectively. Rejections B2, C2, D2, and E2 are based on prior art disclosures of offspring sexually produced by in vitro fertilization of cattle, sheep, pigs, and goats, respectively.

B. Discussion

Findings of fact throughout this Opinion are supported by a preponderance of the evidence of record.

Technological Background: Cloning Methods

The subject matter on appeal relates to clones of mammals. A clone is a genetic copy of an original living thing, in that the clone has the same genetic code as the original living thing. Forms of life that can reproduce asexually—e.g., by fission or budding—naturally produce clones. More "advanced" forms of life tend to reproduce sexually, rather than asexually. Mammals, for example, are not known to reproduce naturally by cloning. An animal that is the product of sexual reproduction receives half of its

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[17] J.J. Matte et al., *Effect of Long-Term Addition of Folic Acid on Folate Statues, Growth Performance, Puberty Attainment, and Reproductive Capacity of Gilts*, 71 J. Anim. Sci. 151-57 (1993).

[18] Luis Ortega-Reyes and Frederick D. Provenza, *Experience with Blackbrush Affects Ingestion of Shrub Live Oak by Goats*, 71 J. Anim. Sci. 380-83 (1993).

genetic complement from one parent, and the other half from the other parent.

The 233 application explains cloning in the following general terms: an embryo is "reconstructed" by transferring [*in vitro*] a nucleus from a donor embryo to an "enucleated oocyte" [an egg cell with its nucleus removed, either physically or functionally] to allow "the production of genetically identical individuals." (Spec. 1, ll. 7-10.) The 233 Specification teaches that nuclear transfer can be accomplished "most conveniently" by cell fusion (*id.* at 12, ll. 32-33), although other suitable techniques are said to include microinjection (*id.* at 13, ll. 33-35). The resulting reconstructed embryo is subsequently implanted into a host mother, and development proceeds "to term," i.e., to produce live offspring. (Spec. 2, ll. 27.)

According to the 233 Specification, a problem with the prior art approach is that there are only 32 to 64 cells per embryo at the stage most widely used to obtain donor nuclei for the cloning of farm animals. (*Id.* at 1, ll. 14-20.) The nuclei of these embryonic cells are used because they are rendered "totipotent" upon transfer into a prepared oocyte. That is, they gain the capability of directing the development of "extra-embryonic lineages, i.e., the placenta" (*id.* at 4, ll. 9-12) as well as all the cell lines in the embryo itself.[19] More plentiful sources of cells are said to be desirable,

[19] Nuclei that can direct the development of all cell lines of the embryo are referred to as "pluripotent" or "multipotent." (Spec. 4, ll. 14-17.) The nuclei of such cells (which include "embryonic stem cells" and "induced pluripotent stem cells") are too differentiated to be totipotent, and their development clock must be "reset" to be usable in the disclosed cloning process.

and cells that can be maintained in culture are said to be especially sought in the art in order to enable "the production of large numbers of identical offspring over a long time period." (*Id.* at 1, ll. 21-30.) The ability "genetically to modify and/or select cell populations of the required genotype (e.g., sex) prior to embryo reconstruction" is also disclosed to be advantageous. (*Id.* at ll. 31-33.)

Somatic cells (i.e., differentiated, non-germ line cells) are said to satisfy these requirements. (*Id.* at 4, first paragraph.) The difficulty with somatic cells, however, is that once a cell has developed—differentiated—into a particular tissue type, it cannot, under normal conditions, become some other tissue type. Thus, to be useful for cloning, the developmental clock of the nucleus to be transferred must be "reset" so it can develop into all cell types of the animal. (*Id.* at 2, last para.) According to the 233 Specification, the critical discovery was that

> changes in the donor nucleus which are observed after embryo reconstruction and which are required for efficient nuclear transfer can be induced in the nuclei of cells prior to their use as nuclear donors by causing them to enter the quiescent state. This fact has been exploited in the present application.

(*Id.* at 4, l. 32 to 5, l. 3.)

The 233 Specification discloses generally that the donor cell is not restricted to a particular donor cell type:

> All cells of normal karyotype, including embryonic, foetal and adult somatic cells, which can be induced to enter quiescence or exist in a quiescent state *in vivo* may prove totipotent using this technology. The invention therefore contemplates the use of an at least partially differentiated

> cell, including a fully differentiated cell. Donor cells may be, but do not have to be, in culture.

(*Id.* at 7, ll. 15-24.)

The Specification does not disclose the existence of systematic differences in the clones that arise from the use of nuclei transferred from different donor types. The critical disclosed feature for cloning is that the donor nuclei have been induced to enter the quiescent stage.

As for the influence of the oocyte into which the donor nucleus is transferred, the 233 Specification teaches that "[a]nimals produced by transfer of nuclei from a source of genetically identical cells share the same nucleus, but are not strictly identical as they are derived from different oocytes. The significance of this different origin is not clear, but may affect commercial traits." (*Id.* at 19, ll. 7-11.) The Specification cautions further that "[i]t remains . . . to consider whether it is possible or necessary in specific situations to consider the selection of oocytes." (*Id.* at ll. 17-21.) Thus, as in the case of the donor nuclei, the Specification does not disclose any systematic differences in the clones that arise from the nature of the recipient oocyte.

The Claimed Subject Matter: Clones

The claimed subject matter is a live-born clone of certain "pre-existing non-embryonic [claim 164, non-foetal] donor mammal[s]." We understand these recitations mean that the donor nucleus comes from a "somatic," i.e., differentiated, cell that is no longer totipotent and that is no

longer pluripotent. To be clear, we emphasize that the patentability of the disclosed process of making the claimed clones is not an issue in this case.[20]

Based on the disclosed cloning procedures, the minimum genetic identity is a complete copy of the nuclear DNA, surrounded by the nuclear proteins and other molecules present in the donor nucleus. In those cases in which the nuclear donor, the oocyte donor, and the implant host are the same creature, and in which nuclear transfer is effected by fusion of quiescent cells from the implant host with enucleated oocytes from the implant host, the genetic identity extends to the mitochondrial DNA of the donor. In such a case, the intracellular environments in which the nuclei of the clone develop, and the intrauterine environment in which the clone itself develops is as close to "self" as possible.[21] At the other extreme, the nuclear donor, the oocyte donor, and the implant host are unrelated beyond being members of the same species.[22]

Roslin argues that "[t]he term 'clone' should be viewed as a structural limitation." (Br. 18, l. 6.) In other words, Roslin argues, "the clone must be a structural 'copy' of the parent. It must have the same genetic complement as its donor animal." (*Id.* at ll. 10-11.) However, beyond the identity of the

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[20] The general nuclear transfer process is now known as "somatic cell nuclear transfer," and the cloning process is referred to as "SCNT" cloning.

[21] It may be observed that, in nature, a mammal always develops in a "non-self" environment.

[22] More abstractly, one might imagine a "clone" based on the artificial synthesis of the complete nuclear DNA of a pre-existing "donor" mammal, although creating such a creature does not appear to be within the skill of the present state of the art.

nuclear DNA, the viability of the offspring, and the implicit requirement that the clone be phenotypically "normal," the term "clone" appears to impose no further structural or functional requirements.

Roslin insists further that the claims should not be considered as being product-by-process claims. (*Id.* at 17, l. 10-17, l. 6.) Because it is not clear, however, what differences arise in the scope of the claim as far as satisfying the criteria for patentable subject matter under § 101, we defer consideration of the product-by-process issue to the discussion of the rejections over prior art.

§ 101, Patentable Subject Matter

Section 101 of Title 35, United States Code, reads, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." The Supreme Court has long held that "this provision contains an important exception, namely '[L]aws of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo Collaborative Services v. Prometheus Labs., Inc.*, ___ U.S. ____, ____, 132 S. Ct. 1289, 1293 (2012) (citations omitted). In other words, an invention may fall squarely within one of the named categories of invention, but still not be patentable subject matter. As the Court has observed, "[w]hile these exceptions are not required by the statutory text, they are consistent with the notion that a patentable process must be 'new and useful.'" *Bilski v. Kappos*, 130 S. Ct.

3218, 3225 (2010).[23] The Court has explained that "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Id.*, *quoting Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

Importantly, the Court rejected the suggestion—advanced by the Government in *Mayo*—that the §§ 102, 103, and 112 inquiries be substituted "for the better established inquiry under § 101" because "to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do." *Mayo*, 132 S. Ct. at 1304. More specifically, and perhaps most relevant to the present appeal, the Court observed that "§§ 102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections." *Id.*

In the present appeal, the "phenomenon of nature" is the most relevant exception, as the concrete character of a composition of matter or manufacture obviates concerns about abstract ideas or laws of nature. The most relevant cases decided by the Court regarding the status of compositions of matter or manufactures as patentable subject matter are *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (genetically modified bacteria found to be patentable subject matter), and arguably *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) (a mixture of bacteria that do not mutually inhibit one another found to be not patentable subject matter).

[23] The discussion of the statutory term "new" in *Campbell I* should be read in this light.

In these cases, the Court weighed the evidence regarding whether the claimed subject matter was "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'" *Chakrabarty*, 447 U.S. 309-10 (1980), *quoting Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887). The genetically modified bacterium claimed by Chakrabarty was found to be "a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101." *Id.* at 310. The Court (*id.*) then contrasted the invention at issue in *Funk Brothers*, in which the claimed "aggregation of select strains of the several species into one product" was found to be "an application of that newly-discovered natural principle [i.e., the qualities of mutual non-inhibition]." *Funk Bros.*, 333 U.S. at 131. The Court explained that, notwithstanding the ingenuity of the discovery of the natural principle of non-inhibition, the combination was nonetheless not patentable subject matter because each species of bacteria remained the same:

> Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. *The bacteria perform in their natural way*. Their use in combination does not improve in any way their natural functioning. *They serve the ends nature originally provided and act quite independently of any effort of the patentee*.

(*Id.*; emphasis added.)

The Federal Circuit recently summarized the differences between products of nature and human-made inventions in the following words:

> One distinction . . . between products of nature and human-made invention for purposes of § 101 turns on a change in the claimed composition's identity compared with what exists in nature. The Supreme Court has drawn a line between compositions that, even if arrayed in useful combinations or harnessed to exploit newly discovered properties, have similar characteristics as in nature, and compositions that human intervention has given "markedly different," or "distinctive," characteristics.

Myriad, 689 F.3d at 1327-28 (citations omitted.)

We must consider, therefore, the characteristics of the *claimed* clones, and inquire whether they have, as a result of human intervention, markedly different, or distinctive characteristics such that the clones are eligible for patent protection.

Clones within the scope of the claims do not differ genetically from the nuclear donor. Because a clone has the same DNA "instruction set" as the nuclear donor, it is more like that nuclear donor (which may also have been the oocyte donor and the host mother) than any other non-human mammal of that species that is not a clone of that donor. Thus, clones are not like the genetically modified bacteria invented by Chakrabarty, which were different genetically as well as phenotypically from any bacteria found in nature. Rather, clones are intended to be as much like the nuclear donor as possible. Indeed, the salient difference between the clone and all other non-clones of that species is that the clone is more like the donor than any non-clone. Because a clone shares the identical nuclear genome with another individual of that species, it represents the "best possible copy" of

the donor, even if it is not identical. Phenotypic differences—i.e., differences in appearance due to differences of expression of the same DNA instruction set—do not change a clone of a donor into a non-clone.

At first glance, a "copy" of a pre-existing thing seems unlikely to be eligible for patent protection under § 101 because it is not "new," to use the words of the statute. To use the categories of exception named by the Court, such a "copy" appears to be a copy of a product of nature, and therefore, although it may be called a composition of matter or a manufacture, it appears to be excluded from being patentable subject matter. The question is, therefore, are the differences between a clone and copies of other compositions of matter or articles of manufacture of a kind sufficient to make clones patentable?

The differences between the clone and the nuclear donor cited by Roslin in the principal Brief are said by counsel to include different color patterns, different iris patterns, and behavioral differences. (Br., para. bridging 26-27.) These differences do not, on the present record, result in a creature having a name, character, and use distinctive from those of the donor. A further difference identified by Roslin between the clone and the donor is said to be that the clone is a time-delayed genetic copy of the donor. (Br. 27, 1st full para.) The time-delayed character of the clone, Roslin urges, permits the use of the clone as an alternative, time-delayed source of nuclear genomic material of the donor mammal that does not depend on the continued existence of the donor mammal. (*Id.* at 2d full para.) The difficulty with the time-delayed characteristic is that it is true of any copy of an original. Roslin's further arguments (Br. 28-29) that a clone is not

anticipated, and therefore "new" because of the manifold phenotypic differences between the clone and the parent are not persuasive because these different characteristics do not result in a thing having a distinctive name, character, and use from the donor.

The clone, being a close copy, has the same uses as the donor, and can be said, much like the bacteria denied patentability in *Funk Brothers*, to "serve the ends nature originally provided and act quite independently of any effort of the patentee." It can equally well be said that "there is no change in the name, appearance, or general character of the clone." By these measures, the clone is a "copy" of the nuclear donor mammal, produced according to the same master plan (the nuclear DNA), and differing, in largely unpredictable and uncontrollable ways as the result of as yet largely unknown causes and mechanisms, from the pre-existing donor.

At oral argument, counsel was asked in what way the claimed clones—very complicated, very detailed copies—differed as patentable subject matter, from an exact copy of a very complicated, very detailed inanimate object, such as a pile of sand (stipulating utility for such an object). (Tr. 12, l. 20, to 13, l. 2.) Counsel responded that the status of the clone as a living thing was the essential difference, because living things exist for a certain time period, and that the continuity of the [genetic] information was, prior to the claimed clones, lost, or diluted. (*Id.* at 12, ll. 3-14.) "But," counsel continued, "because of the fact that it's living, into this new timeframe, now you could clone it again and potentially keep that going." (*Id.* at ll. 17-18.) The Federal Circuit, however, has stated, "we think the fact that microorganisms are alive is a distinction without legal

significance and that they should be treated under § 101 no differently from chemical compounds." *In re Bergy*, 596 F.2d 952, 975 (CCPA 1979) (*Bergy* is the consolidated opinion on appeals by Bergy and by Chakrabarty. Certiorari was sought and granted as to both cases. *Bergy* was subsequently dismissed as moot, 444 U.S. 1028 (1980), and the judgment of the CCPA as to Chakrabarty was affirmed: *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (deciding that the live, human-made microorganism claimed by Chakrabarty is patentable subject matter under § 101).) Thus, these arguments are not persuasive that the genetic identity gives the clone "markedly different" or "distinctive" characteristics from the donor.

In the Supplemental Brief, Roslin argues that the holding by the Federal Circuit in *Myriad* that isolated DNA molecules are patentable subject matter should extend to the claimed clones because "through human intervention, the clone has been isolated from the normal process of sexual reproduction.: (Supp. Br. 6, ll. 14-15.) Roslin argues further that the "clones reduce a portion of nature, a single donor mammal's genetic information, to a concrete form, a clone with the intact genetic information of the donor mammal." (*id.* at 7, l. 14 to 8, l. 1.)

While these features may form a basis for patenting processes of using clones or materials derived from clones, they do not suffice to remove the claimed clones from the categorical exception of being a "phenomenon of nature," and therefore unpatentable subject matter.

The disclosed clones are "copies" of pre-existing donor mammals, in that the same nuclear DNA instruction set is used to direct the development of the clone. The practically inevitable differences between the pre-existing

donor and the clone do not appear to arise out of human control of the developmental process or human control of the environment in which the development occurs. Rather, the developmental process and the environment, including the non-DNA materials in the nucleus that have some role in the regulation of the development, are so complicated and so delicate that they overwhelm the role of "the hand of man" in the ultimate product. A clone—as good a copy as can be made—of a pre-existing natural phenomenon (in this case, one of the four named mammals), is not a new mammal with markedly different characteristics than any found in nature.

That the extraordinary technical accomplishments that are required to produce the clones constitute patentable subject matter, subject to the further requirements of Title 35, has not been questioned. Moreover, while certain processes of making or using the clone or of using certain materials (e.g., tissues or organs) produced by the clone might well be patentable processes, the clone itself—because it is a copy of a pre-existing donor that is not markedly different from that donor, is not patentable subject matter, even though it is "made by the hand of man."

The hybrid 102/103 Rejections Over Clones From Embryonic Donors

It is well settled that "[w]here . . . the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (citation omitted). In such a case, the burdens of production

and persuasion are shifted to the applicant. The court explained further that "[w]hether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products." (*Id.*, citation omitted.) The rejection of product-by-process claims during examination before the PTO has followed a similar analysis. *See, e.g.*, *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (citing *In re Thorpe,* 777 F.2d 695, 697-98 (Fed.Cir.1985), "wherein the examiner's rejection of product-by-process claims under §§ 102, 103, based on similarity of reactants, reaction conditions, and properties, amounted to a *prima facie* case of unpatentability.") As is the case for a "pure" product claim, a product-by-process claim is rejected properly as anticipated or obvious in view of any prior art product, no matter how made, that is identical or substantial identical to an embodiment within the scope of the claim.

Roslin argues (Br. 29-30) that the Examiner improperly ignored the "non-embryonic" limitation of the claims, which, Roslin insists, are pure product claims, not product-by-process claims (*id.* at 17-20). We hold, however, that the recitation that the donor be "non-embryonic" has patentable weight only to the extent that a clone from a non-embryonic donor differs in a substantial way from a clone from an embryonic donor. Thus, to distinguish clones based on the nuclear donor, the structural features that differ due to the embryonic versus the non-embryonic state of the donor must be identified and shown to be substantial. Although Roslin

points to some of the differences said to exist between embryonic and non-embryonic donors (*id.* at 31-32), Roslin has not come forward with probative evidence of what ways the resulting clones would be distinctive, one from the other.[24]

In the present case, Roslin has not, in response to the Examiner's rejections over prior art clones produced from embryonic cattle, sheep, pig, and goat donors, explained, with appropriate supporting evidence, in what ways the resulting live born clones differ from clones made from non-embryonic (or further non-foetal) donors. Rather, Roslin has attempted through attorney argument to distinguish the claimed clones by pointing to the embryonic characteristics of the donor. But, attorney argument cannot take the place of evidence in the record. *In re Walters*, 168 F.2d 79, 80 (CCPA 1948). Although nuclei from the less-developed, less differentiated embryonic cells may be easier to reprogram for complete development following nuclear transfer, Roslin has not shown on the present record that the clones from embryonic nuclei differ in any substantial way from the claimed clones. Put another way, Roslin has not shown how a person having ordinary skill in the art, presented with a sheep produced by nuclear transfer cloning from a sheep embryo cell and with a sheep produced by nuclear transfer cloning from a somatic sheep cell, would determine which was

[24] Roslin's argument might have more weight if the claims were patented and the issue were infringement or validity. *Abbott Labs v. Sandoz Inc.*, 566 F.3d 1282, 1291-295 (Fed. Cir. 2009) (en banc in part III.A.2, adopting the rule in *Atlantic Thermoplastics Co. v. Faytex Corp.,* 970 F.2d 834 (Fed. Cir. 1992) (*see especially* 846-47, explaining the difference between patentability standards during examination of an application for patent and validity or infringement standards during litigation involving a patent)).

which. Nor has Roslin shown that the differences would be of a kind sufficient to overcome the Examiner's prima facie case of unpatentability.

Thus, on the present record, Roslin has not shown how the prior art clones differ from the claimed clones, except by the source of the genetic information. We conclude that error has not been shown by a preponderance of the evidence in the Examiner's rejections under §§ 102(b)/103 over the clones from embryos.

The Hybrid 102/103 Rejections Over Prior Art IVF Animals

To be anticipatory, a reference must describe, either expressly or inherently, each and every claim limitation, arranged or combined as required by the claimed invention, and enable one of skill in the art to practice an embodiment of the claimed invention without undue experimentation. *See In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

The present claims are drawn to clones, which have, by definition, the same nuclear genetic complement as a previously existing animal. Thus, while one might not be able to tell the difference between a clone and a "normal" farm animal such as an animal created by in vitro fertilization (apparently a standard modern-day practice), without access to a genomic data-bank of the parents of the two animals, with that data-base, the difference could be readily determined by standard techniques.

What is claimed is a live-born animal having a nuclear-genetic copy of a pre-existing animal. The DNA that encodes the genetic information is a composition of matter, the structure of which can be determined and compared with other DNAs. Whether the claims to the clone are regarded as

product claims, as urged by Roslin, or as product-by-process claims, as argued by the Examiner, the structural requirement that the nuclear DNA must have existed before cannot be ignored. This structural feature is not met or suggested by the IVF-created mammals cited as prior art by the Examiner.

Accordingly, we REVERSE the rejections over IVF-produced animals.

C. Order

We AFFIRM the rejection of claims 155-159, and 164 under 35 U.S.C. §101.

We AFFIRM the rejection of claims 155, 156, and 164, drawn to clones of cattle, under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Sims.

We AFFIRM the rejection of claims 155, 157, and 164, drawn to clones of sheep, under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of McLaughlin.

We AFFIRM the rejection of claims 155, 158, and 164, drawn to clones of pigs, under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Prather.

We AFFIRM the rejection of claims 155, 159, and 164, drawn to clones of goats, under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Yong.

We REVERSE the rejection of claims 155, 156, and 164, drawn to clones of cattle, under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Zinn.

We REVERSE the rejection of claims 155, 157, and 164, drawn to clones of sheep, under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Aldrich.

We REVERSE the rejection of claims 155, 158, and 164, drawn to clones of pigs, under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Matte.

We REVERSE the rejection of claims 155, 159, and 164, drawn to clones of goats, under 35 U.S.C. § 102(b), alternatively under 35 U.S.C. § 103(a) in view of Ortega-Reyes.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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